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**Pastrick et al.**

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(54) **MEDICAL TRAINING DEVICE**

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(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1406 days.

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**G09B 23/30** (2006.01)

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CPC ..... **G09B 23/28** (2013.01); **G09B 23/30** (2013.01)

(58) **Field of Classification Search**  
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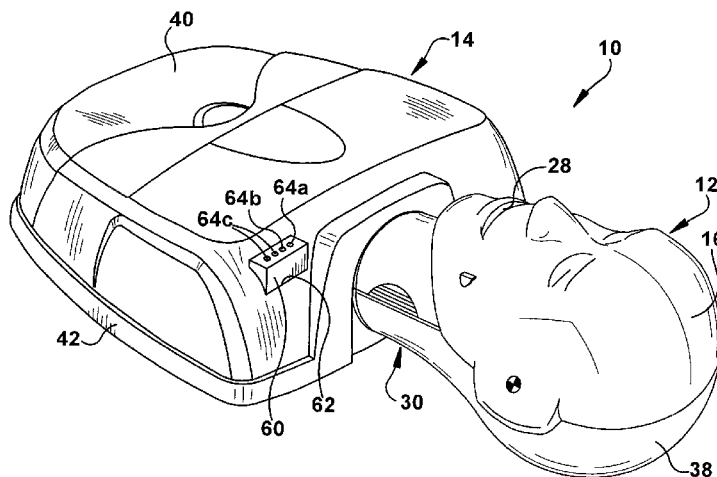
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(57) **ABSTRACT**

A medical training device with an improved clam shell type torso arrangement. An improved two-piece tiltable head feature, including mechanical mounting structure for secure attachment of an improved lung bag or face shield. The head also includes an improved nose feature to provide a more realistic representation of nasal cartilage, and an improved neck assembly. Additionally, an electro-mechanical indicator device is provided to show real time feedback of the CPR compression rate being administered by a student on the training manikin of the present application. The feedback by the device may be provided preferably by visual indicators, but may also have, or alternatively have, audio indicators or signals, such as words or sounds, to indicate whether or not the student is compressing within the preferred rate range, and/or the degree of variance in the student's compression sequences.

**10 Claims, 9 Drawing Sheets**



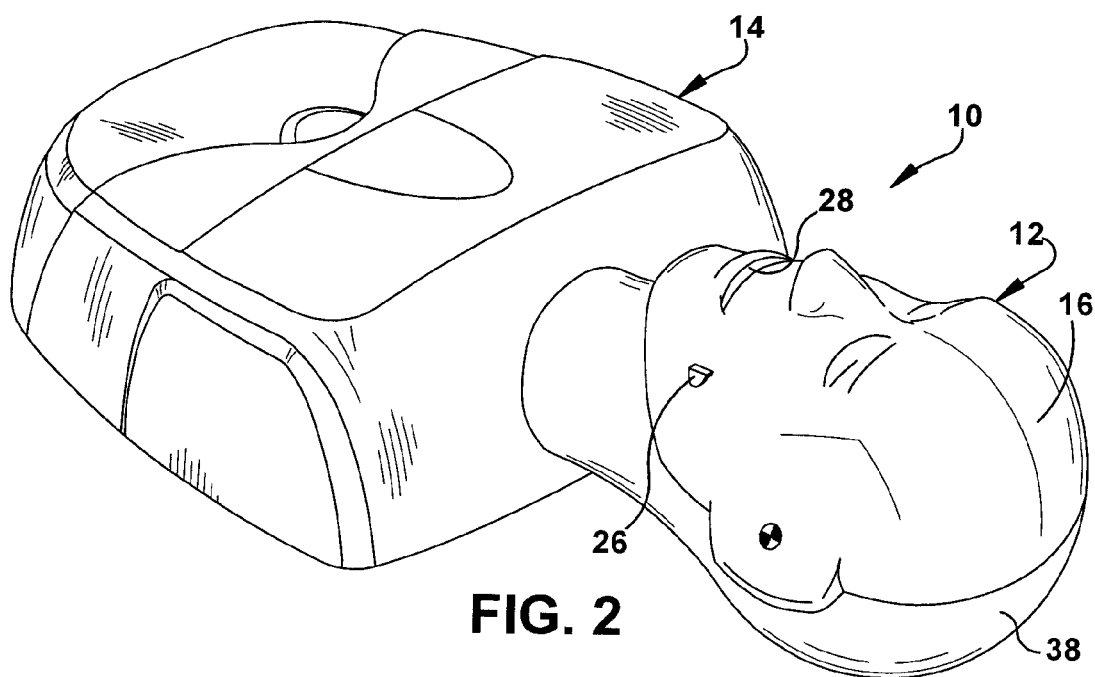
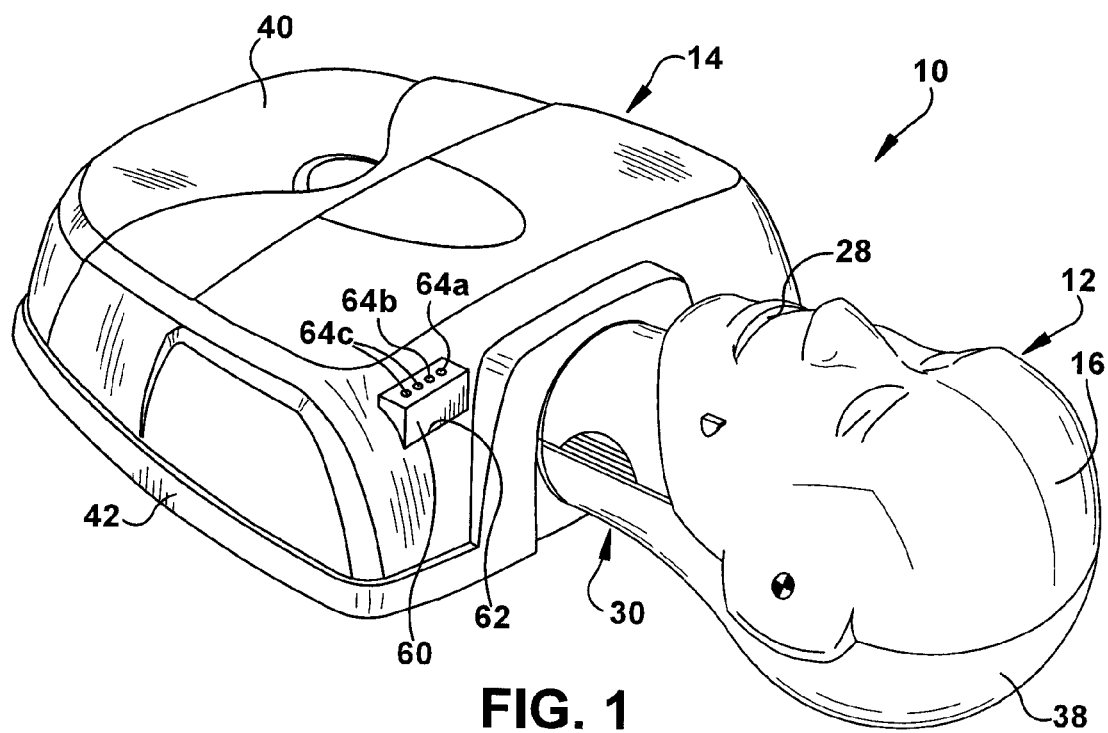
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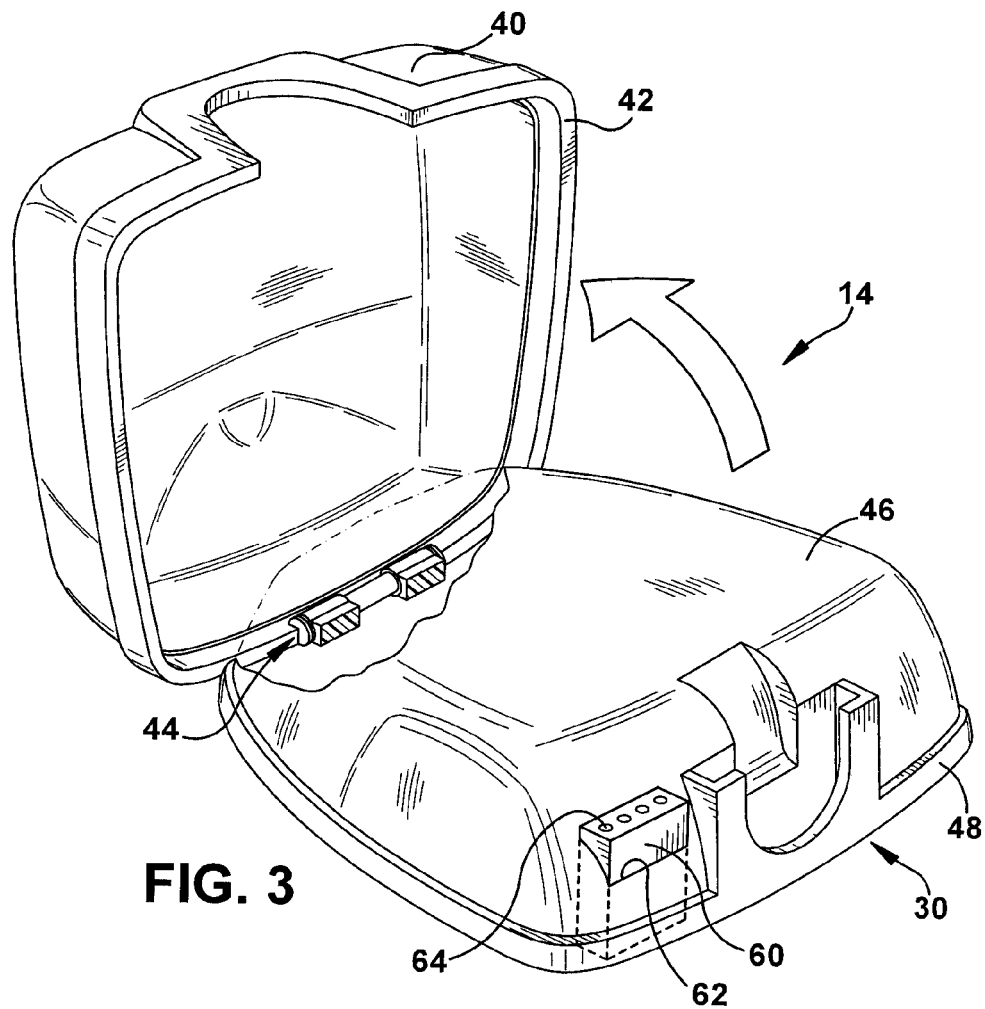
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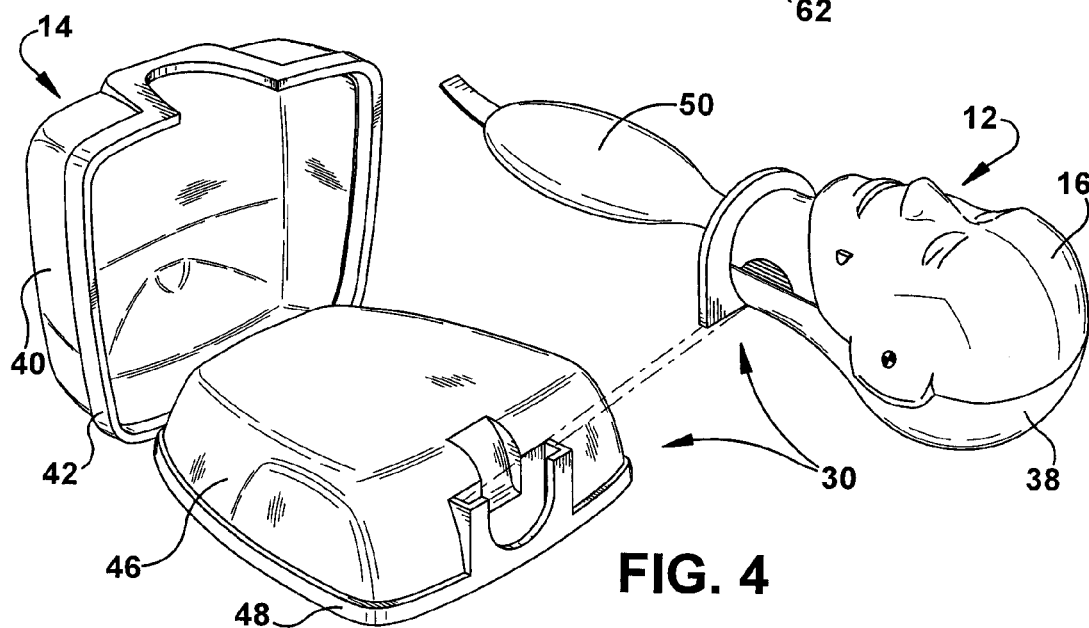
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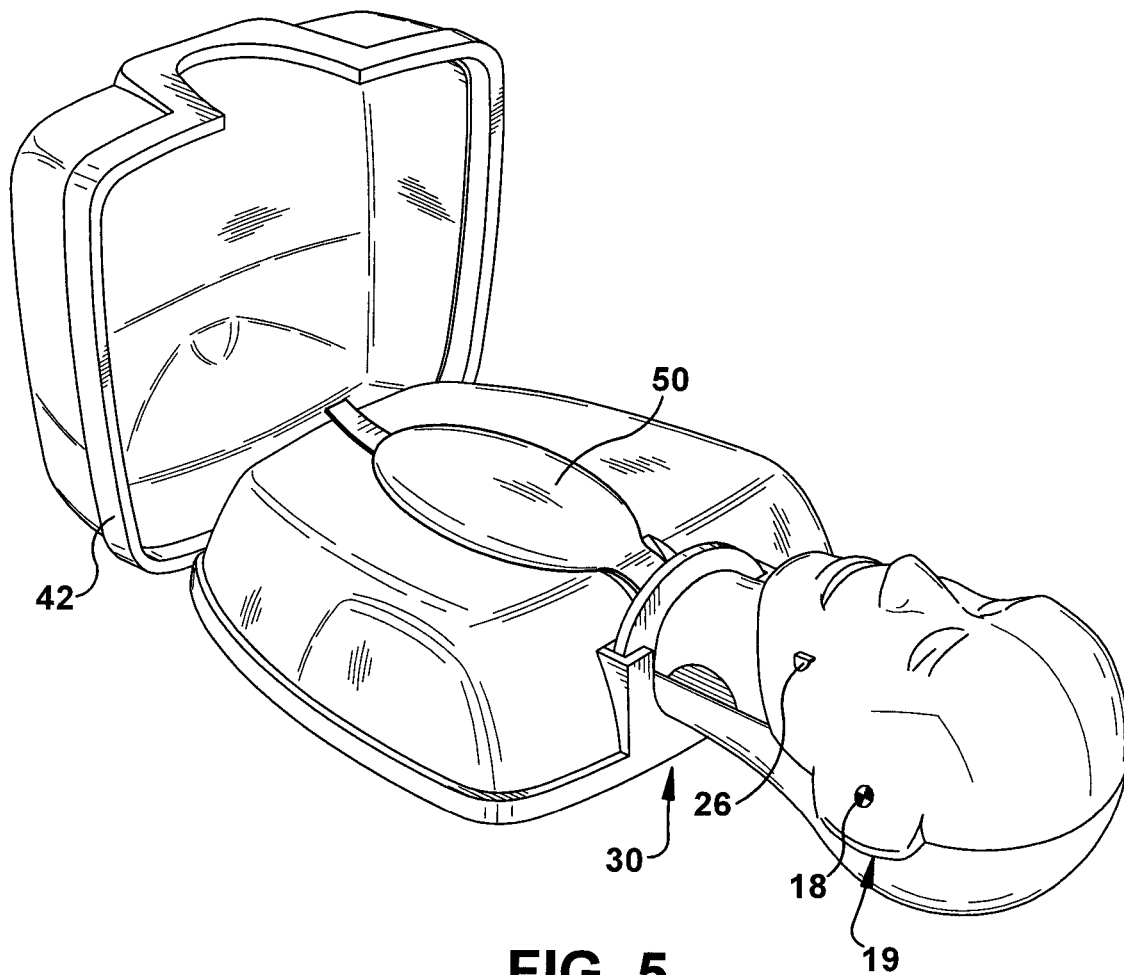


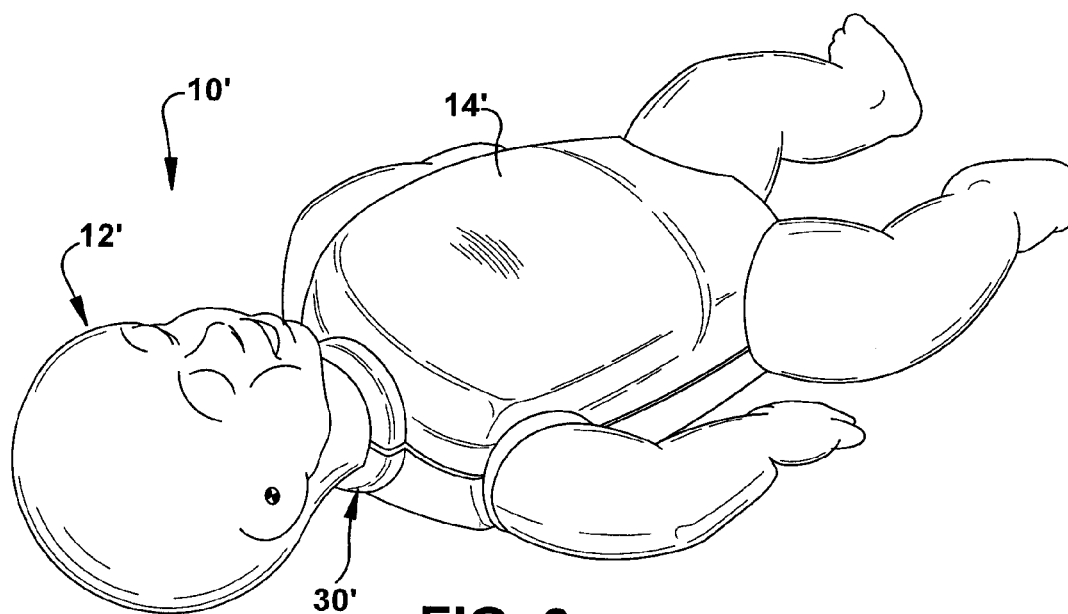


**FIG. 3**

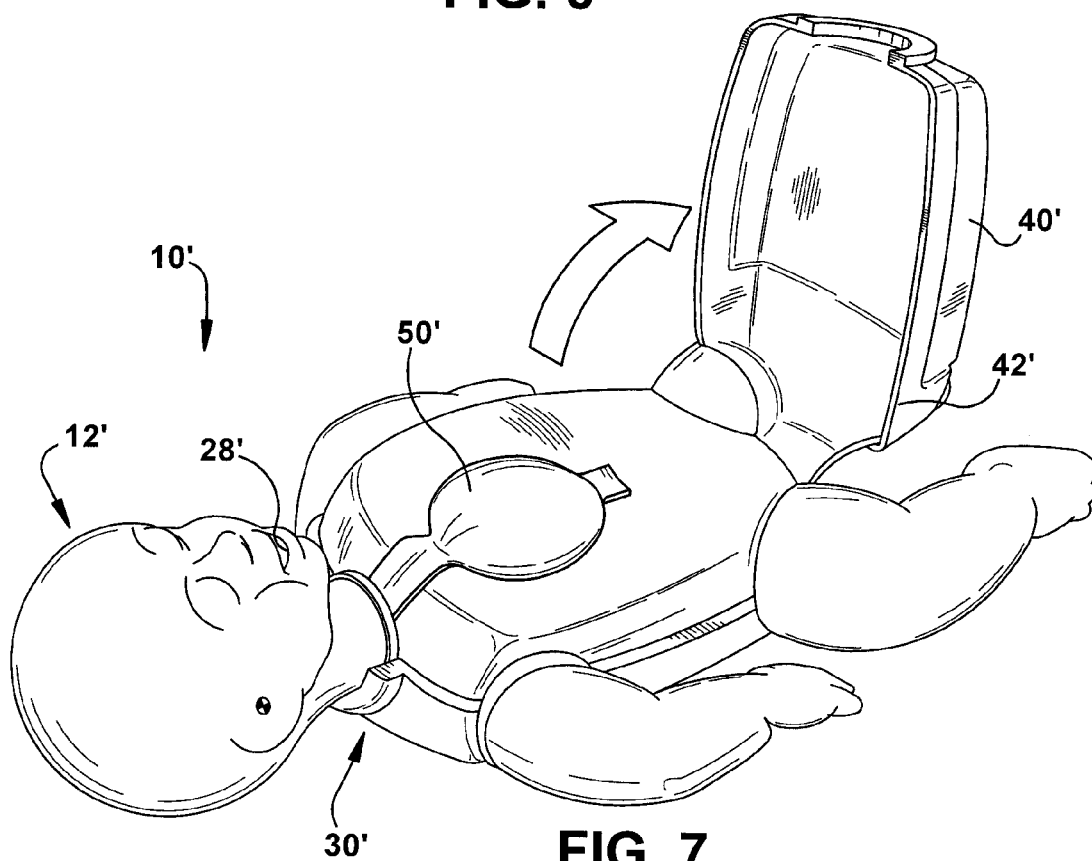


**FIG. 4**

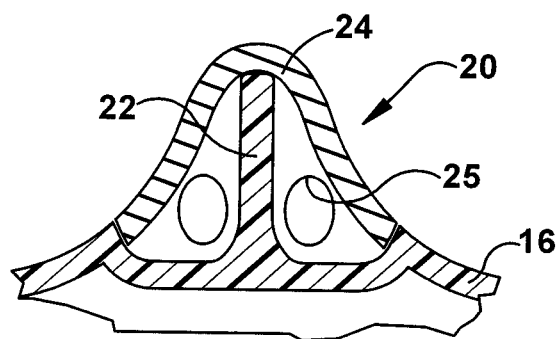
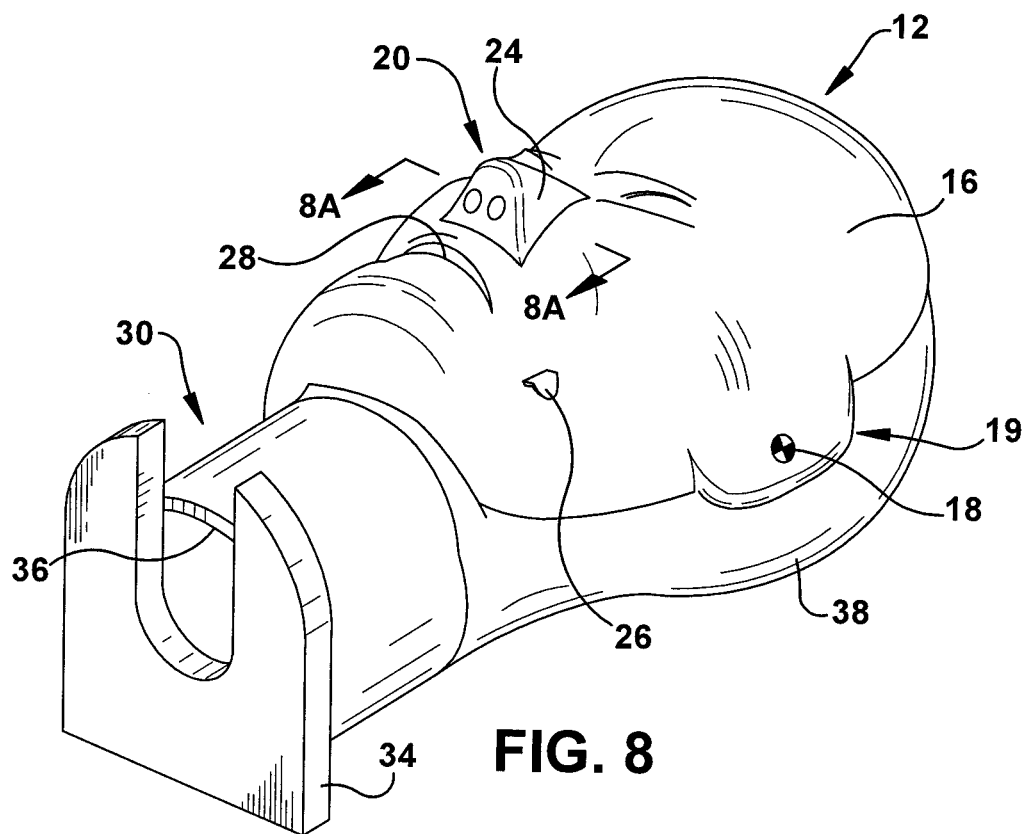


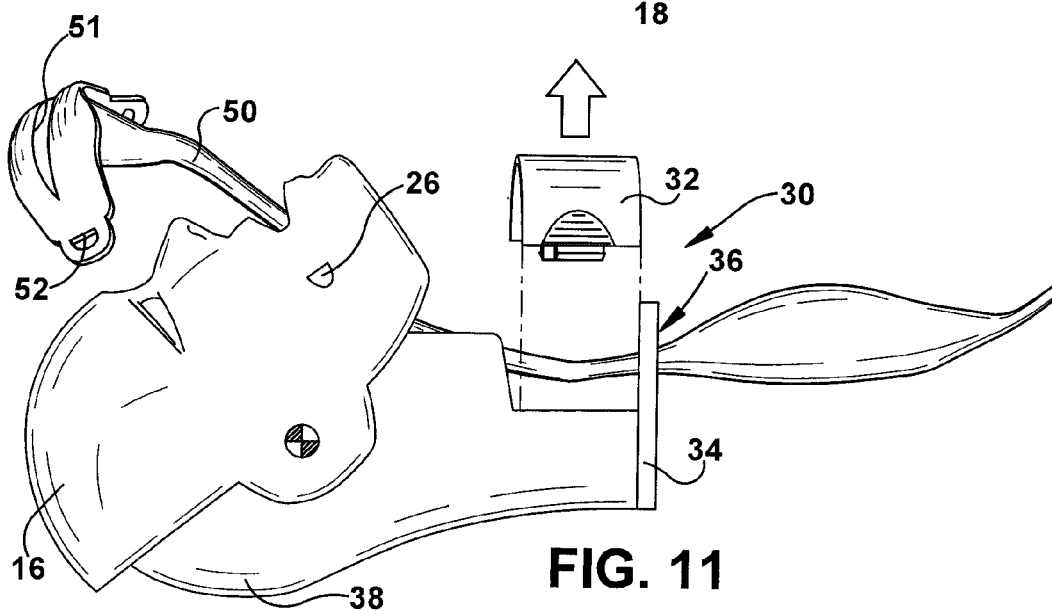
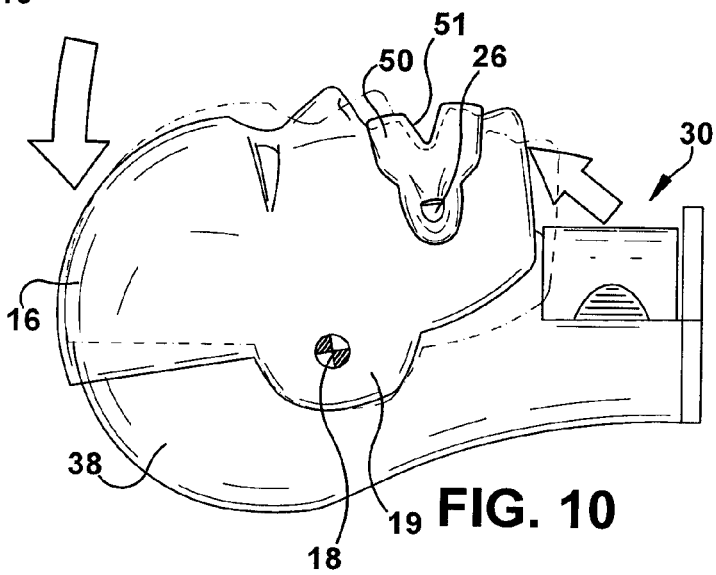
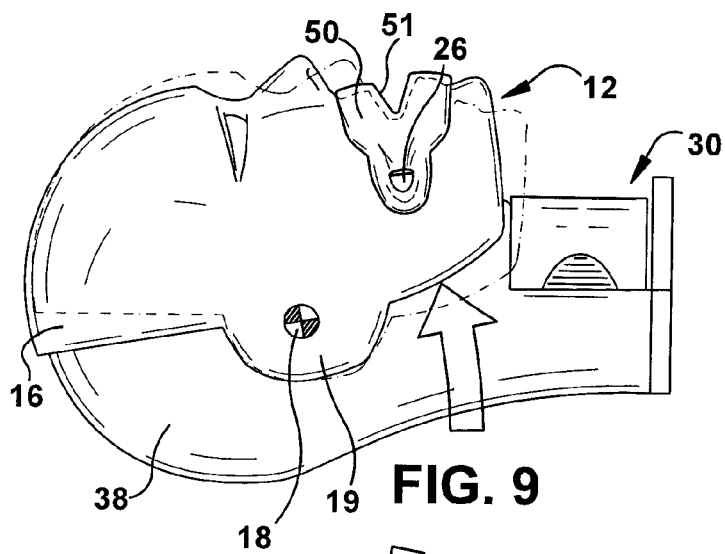


**FIG. 6**

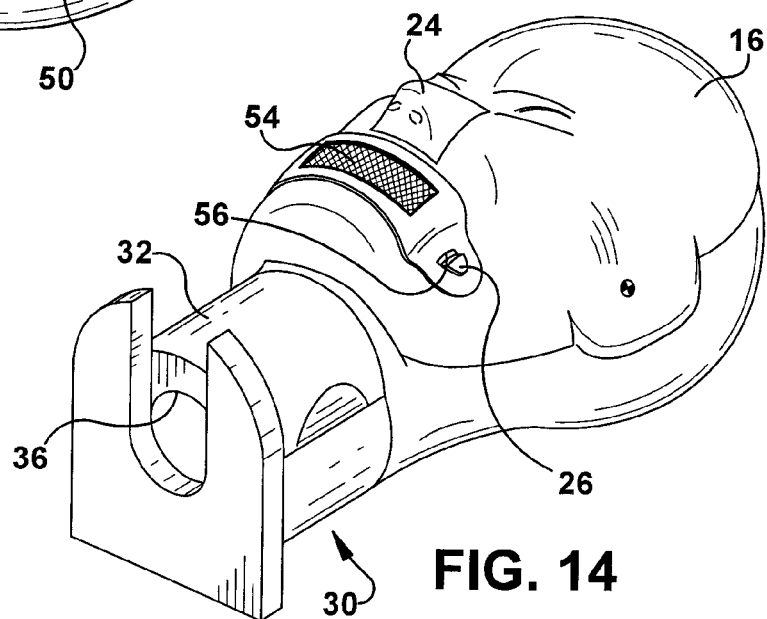
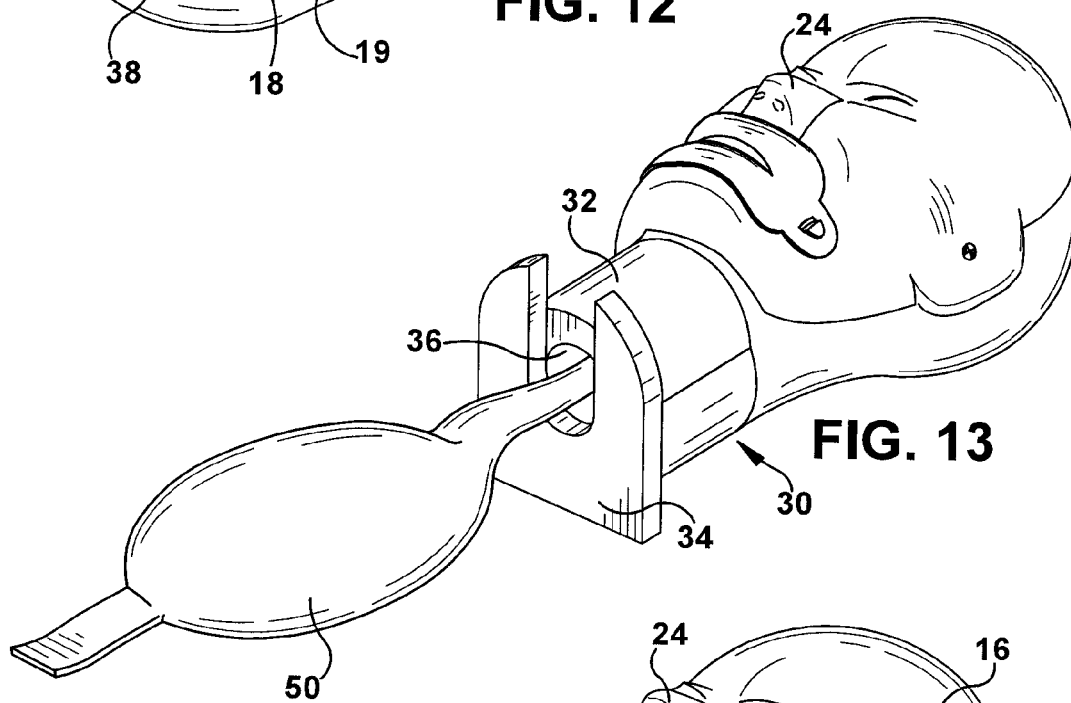
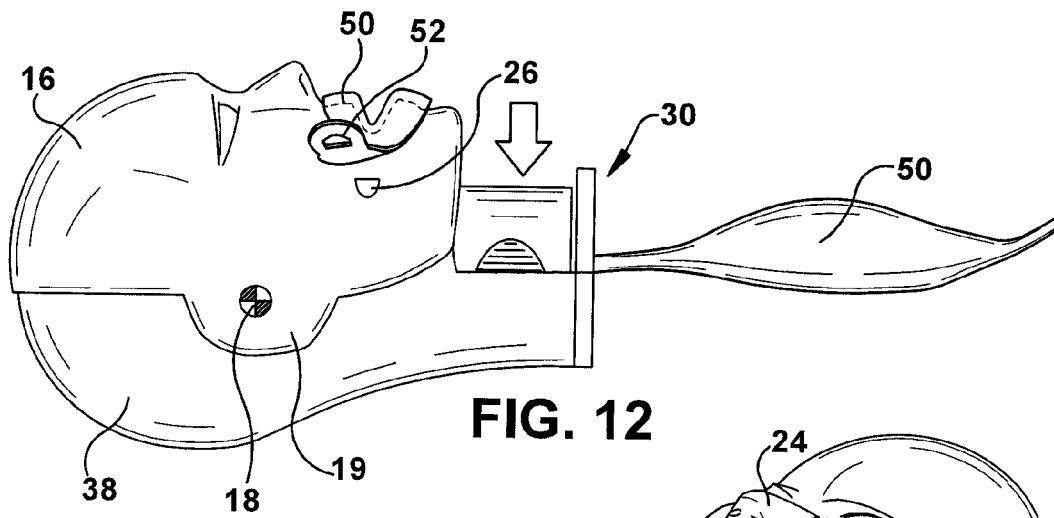


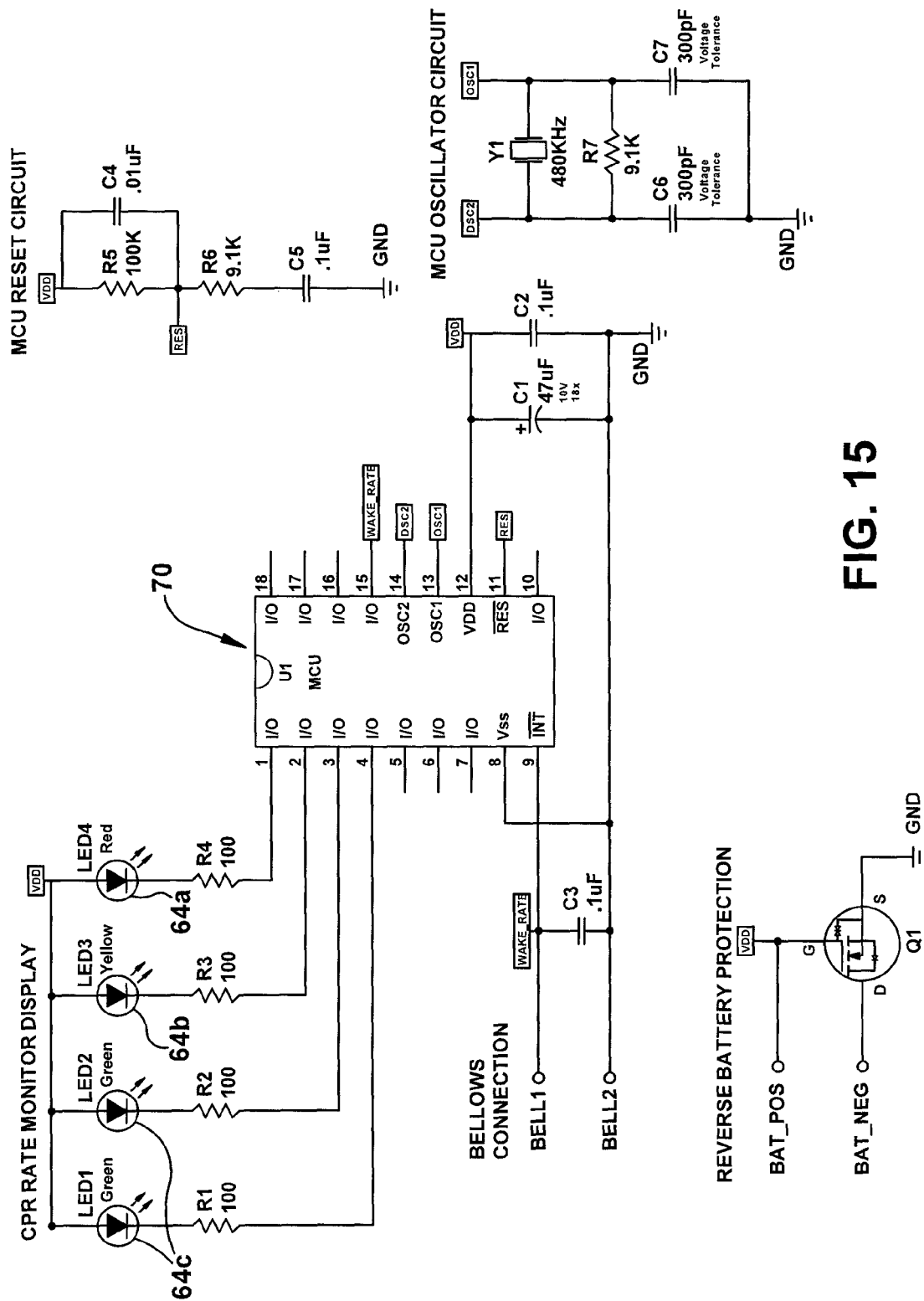
**FIG. 7**

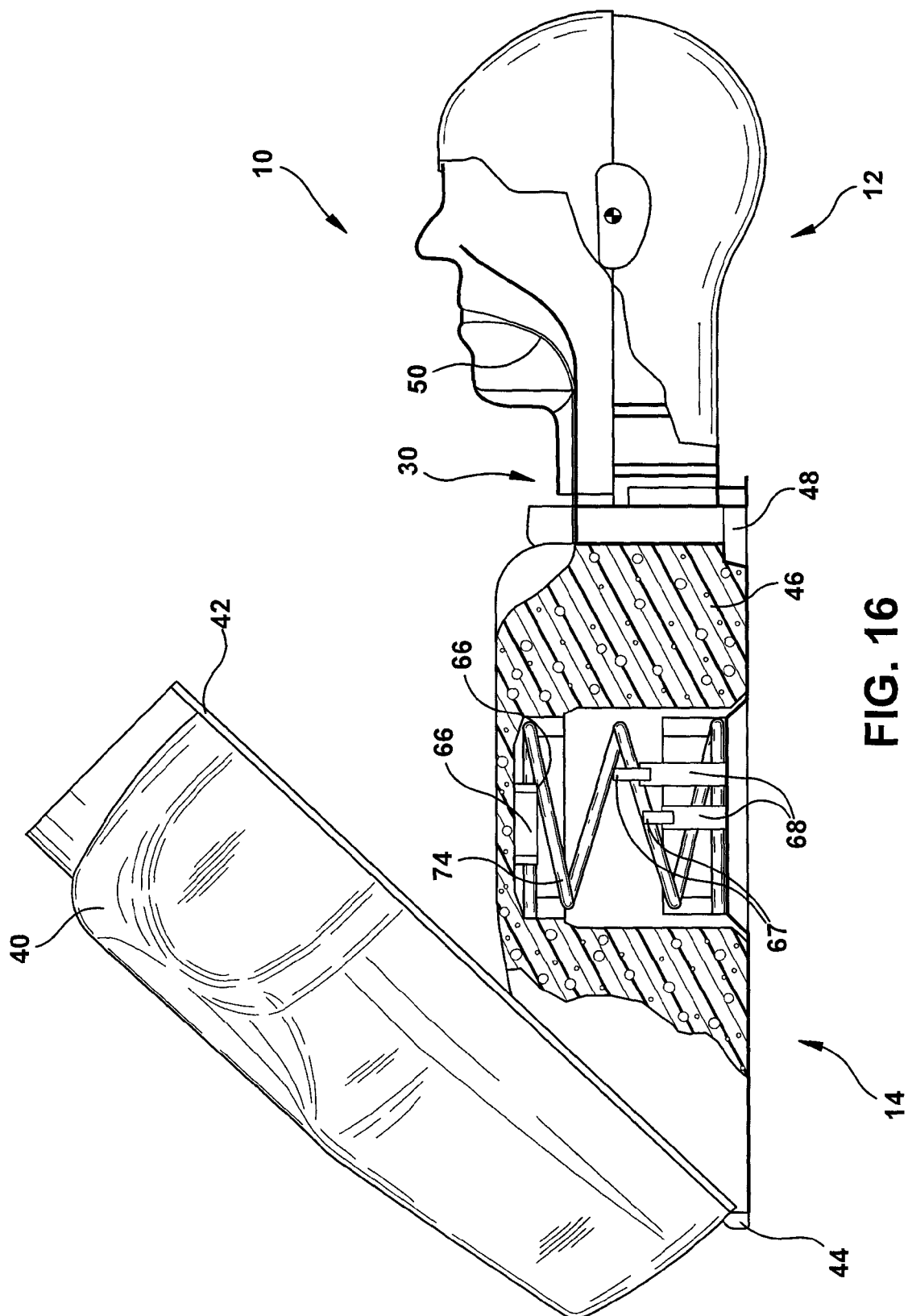












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**MEDICAL TRAINING DEVICE****CROSS REFERENCE TO RELATED APPLICATION**

The present application claims priority from U.S. Provisional Patent Application Ser. No. 60/713,276 filed Sep. 1, 2005.

**FIELD OF INVENTION**

The present application is directed to an improved medical training device, and more particularly to a medical training manikin having improved features and accessories.

**BACKGROUND**

Numerous solutions have been offered in the past to provide an inexpensive medical training manikin which can be used in a training environment for either a group of trainees or a single individual. It is desired that such medical training manikins are lightweight for easy transportation to the training site, as well as simple and quick to assemble, readily able to be cleaned or otherwise maintained in a sanitary condition, easy to use, and capable of substantially simulating the functions and responses of a human patient.

Prior art devices which have attempted to provide solutions to the above include U.S. Pat. Nos. 6,500,009, 5,330,514, 5,468,151, 4,984,987 and 5,885,084.

**SUMMARY OF THE INVENTION**

The present medical training device provides a number of improved features over prior products. The present product has an improved clam shell type torso arrangement. An improved two-piece tiltable head feature is also provided. A head may include mechanical mounting structure for secure attachment of an improved lung bag or face shield. The head also includes an improved nose feature to provide a more realistic representation of nasal cartilage, and an improved neck assembly. Additionally, an electro-mechanical indicator device is provided to show real time feedback of the CPR compression rate being administered by a student on the training manikin of the present application. The feedback by the device may be provided preferably by visual indicators, but may also have, or alternatively have, audio indicators or signals, such as words or sounds, to indicate whether or not the student is compressing within the preferred rate range, and/or the degree of variance in the student's compression sequences. The indicator device also includes an automatic on/off sleep feature which is activated by use and non-use of the present training manikin.

**DESCRIPTION OF THE DRAWINGS**

FIG. 1 is a perspective view of the improved medical training device of the present application showing a feedback indicator device.

FIG. 2 is a perspective view of the improved medical training device having mechanical mounting structure on the head for securing a lung bag or face shield.

FIG. 3 is a schematic perspective view of the improved medical training device showing a two-piece clam shell style torso, where one piece is an outer skin portion made of thin pliable material supported by a substantially rigid frame, and a second piece is an inner compressible core material supporting a compression rate indicator device.

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FIG. 4 illustrates a torso similar to FIG. 3, together with a schematic, perspective illustration of the head with a neck assembly and a lung bag prior to engagement with the torso.

FIG. 5 illustrates the engaged torso and head of the device of FIG. 4.

FIG. 6 is a schematic, perspective illustration of the improved medical training device in an infant embodiment.

FIG. 7 is a schematic, perspective illustration of the infant embodiment of FIG. 6 with the pliable cover in an open position with respect to the torso.

FIG. 8 is a schematic, perspective illustration of the head and neck assembly of the improved medical training device of the present application.

FIG. 8A is a cut-away view of an improved nose structure taken along the line 8A-8A in FIG. 8.

FIGS. 9 and 10 are schematic side views of the improved medical training device schematically illustrating the pivoting or tilting movement of the face portion of the head to enable training of the jaw thrust technique.

FIGS. 11, 12 and 13 are schematic side and perspective illustrations of the installation of a lung bag which is secured to the face portion of the improved medical training device at posts or hooks protruding from the face portion.

FIG. 14 schematically illustrates a face shield which is mechanically secured to the face portion of the improved medical training device, and may alternatively be secured over a lung bag.

FIG. 15 schematically illustrates an electrical circuit diagram for a CPR compression rate indicator of the present medical training device.

FIG. 16 is a partial side view, schematic cut-away illustrating the internal sensors, bellows and electrical contacts used in connection with the CPR compression rate indicator of the present medical training device.

**DETAILED DESCRIPTION**

The present application provides an improved medical training device 10. A general view of the adult embodiment of the improved medical training product or device 10 is shown in FIGS. 1 to 5, and the infant embodiment is shown generally at reference 10' in FIGS. 6 and 7. Unless otherwise indicated, many features of the adult and infant embodiments are similar and will be not be distinguished in detail, other than by the use of a prime designation in connection with the infant embodiment.

The improved device 10 includes a torso which is a two-piece clam shell style torso 14. The improved two-piece torso 14 is shown in a variety of positions in FIGS. 3 to 5. One piece of the torso 14 comprises an outer skin portion 40 made of thin pliable material, which is preferably a molded elastomeric material. In the illustrated embodiment of FIGS. 1, 3 to 5 and 7, the pliable skin material 40 is supported by a substantially rigid portion or frame 42. The rigid frame 42 is preferably manufactured of a rigid molded plastic material. The frame 42 and skin 40 may be secured together by molding the two pieces together, or may be mechanically secured together, such as by an adhesive.

The second torso piece is an inner core portion 46 which is covered by the outer pliable skin 40, as shown in FIGS. 1 and 6. The skin and core pieces of the torso 14 may be connected together at a hinge 44 located along one side of the frame 42. The core portion 46 is preferably of a compressible core material, such as a polyurethane foam material, to enable simulated CPR compressions. The second core torso piece 46 may likewise include a base frame 48 for supporting the core portion 46, which base frame 48 may be secured to the core 46

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via adhesive. The frames **42**, **48** may be connected together at the hinge **44** along one side of the rigid support portions or frames. As shown in FIG. **16**, mechanical (such as posts **68**, and a spring or bellows **74**) and electrical components used to perform and measure compressions during operation of the manikin training device, are provided internally of the core **46**.

The torso **14** may include a variety of additional features, such as openings for insertion of additional demonstration organs (not shown), such as for organ transplant trainings. Additional components, such as a simulated heart or lung to be compressed, are shown in FIGS. **6** and **7**.

The use of a two-piece torso **14** allows for fast and easy opening and closing of outer skin **40** for quick installation of a lung bag **50** which enables simulation of lung and chest expansion, particularly through the pliable outer skin portion **40**. As illustrated in the figures, the pliable outer skin portion **40** is molded to include simulated landmarks commonly found on the human torso for use during student training and CPR performance. Additionally, the torso **14** opens to capture and secure a head **12** at a neck assembly **30**. The neck assembly **30** is illustrated in a position generally opposite the hinge **44**. A neck assembly **30** of a variety of designs may be provided as shown in FIGS. **4-5** and **11-12**.

The improved two-piece head **12** is provided with molded head pieces, where the front half or face portion **16** is movable/tiltable, and the back half or base head portion **38** is stationary. A pliable simulated skin cover (not shown) may also be added to the face portion **16** where desired for additional cleanliness or maintenance considerations. Additionally, an improved nose simulation is also provided as best shown in FIGS. **8** and **8A**. The nose includes a simulated rigid nose cartilage portion **22** with a removable pliable cover portion **24** over said simulated rigid nose cartilage **24**. The nose cartilage portion **22** is formed as a part of the rigid face portion **16**, with the removable cover portion **24** formed of pliable material with openings **25** simulating nostrils. The cover portion **24** is snapped into place over the nose cartilage portion **22** to simulate skin.

Pivot points **18**, forming a pivot axis, are provided to interconnect the head and face portions near simulated ears **19** located on opposing sides of the base head portion **38**, which is similar to the natural pivot location of the human head generally at the top of the spine. The use of pivot points **18**, and a single pivot axis, near the ears **19**, eliminates the need for more complex multiple piece pivot designs that are often necessitated by movement of the back of the head.

The front half or face portion **16** of the present device pivots at the pivot points **18**, which define the single pivot axis, or is tilted by either a tilt of the forehead (pressing against the forehead) and lifting the chin as shown by the arrows in FIG. **10**, or by a jaw line lift illustrated by the arrows in FIG. **9**, which enables the training of the jaw thrust technique. In particular, the two pieces of the head may be biased by a spring or weight positioned intermediate the two pieces of the head **12** and internally. The design is preferably such that the jaw of the front or face portion **16** must be moved to a certain level or position before the forehead may be tilted back as provided by the mechanical shape of the pivot mechanism.

The two-piece head pieces are shown in a variety of positions in FIGS. **11** to **16**. In the illustrated embodiments, a neck assembly **30** for attachment to the fixed head portion **38** is also provided. The lung bag **50** also passes through the neck assembly **30** during engagement within the head **12** and torso **14** of the improved medical training device **10**. In the embodiments of FIGS. **2** and **8**, the neck assembly **30** is provided

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integrally with the back head portion **38** such that the lung bag **50** is threaded through a mouth opening **28** in the face portion **16**, through a fixed neck assembly **30** and into the torso **14** positioned intermediate the skin **40** and core portion **46**, as shown in FIG. **7**.

In FIGS. **3** to **5** and **9** to **14**, a base portion **34** of the neck assembly **30** is provided as part of the fixed base head portion **38**, and a second portion is provided as a removable slider cover **32** having finger tabs **33**, which snaps into engagement with the base portion **34** of the neck assembly **30**. In either embodiment, the neck assembly **30** provides an opening **36** for passage of the lung bag **50** intermediate the head **12** and torso **14**.

As shown in FIGS. **11** to **13**, the lung bag **50** is made of thin-film polymer material. To make use of the present device, the lung bag **50** is inserted through the mouth opening **28** of the face portion **16** of the head **14**, through any neck assembly **30**, and laid on the compressible core portion **46** of the torso **14** while the outer skin **40** is in an open position, as shown in FIGS. **3** to **4** and **7**. The lung bag **50** is a sealed bag to be inflated for simulation of lung inflation, with a single opening formed as a mouth portion **51** of the lung bag **50**. Two openings **52** provided on the lung bag at the sides of the mouth portion **51**, which openings **52** are for attachment to protruding portions **26**, such as posts or hooks, extending from the face portion **16** of the head **14**. The lung bag **50** is secured to and held flush against the mouth area of face portion **16** by the mechanical means of the holes or cuts **52** in the thin-film lung bag material. Similar holes or cuts **56** may be provided in a face shield barrier **54** to secure the face shield **54** covering the mouth opening **28** in the face portion **16**, as shown in FIG. **15**, or secured over the lung bag **50** covering the mouth opening **51**, such that two layers of material are mechanically secured to the face portion **15** using the protruding posts **26**. With both the lung bags and face shields of the present design, the thin-film material is secured in place flush to the face portion of the manikin which improves training efficacy by reducing interference of the material, reducing the need for repositioning of the material, and improving the visual presence of the manikin during training.

Finally, the present device provides a novel CPR rate indicator **60**, which is an electro-mechanical device that provides real time feedback of CPR compression rate being administered by the student on the training manikin device **10**, **10'**. The feedback is provided directly by visual indicators and indicates whether or not the student is compressing within the preferred compression rate range. Also, the indicator **60** may inform the student concerning what degree of variance there is in the compressions being administered. Indications may be provided as colored illuminated indicators, a numeric readout, or other visual methods. The CPR rate indicator may be provided as an add on module which is integrated within or connected to an existing manikin product so as to be visually accessible to the student while CPR is being performed. As shown in FIGS. **1** and **3**, the CPR rate indicator **60** is provided integrally with the torso **14**. A window or opening **62** may be provided through the skin **40** and core portion **46** to enable viewing of the indicator **60** during use of the present training device. Alternatively, the indicator **60** may be provided as an original equipment feature to the manikin product **10**, **10'**. Where illuminated indicators **64** are provided, they may be color coded to convey the level of student performance, e.g. red **64a** is poor, for example, less than 60 compressions per minute; yellow **64b** is fair, for example, less than 80 but greater than 60 compressions per minute; green **64c** is acceptable, for example, less than 100 but greater than 80 compressions per minute; the illumination of both green lights **64c** is

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a preferred performance, for example, 100 or more compressions per minute; and if desired, illumination and flashing of both green lights may be a more preferred performance rate. The indication may be provided by colored/illuminated indicators **64a-c**, such as LED's, a numeric readout, or other visual method, as well as by audio signals, such as beeps or tonal sounds. Audio signals may be provided as negative sounds, more positive sounds, most positive sounds and double positive sounds, to convey the desired rate performance information. The indicator module **60** is preferably integrated within, or connected to, the manikin **10** to be visually accessible to the student while CPR is being performed on the manikin training device.

The CPR rate indicator **60** of the present application is preferably desired as a visual training feature, which is passive and, unlike audio feedback, does not interfere with the training exercise. However, it should be understood that audio feedback may have additional desirability under certain training circumstances. Additionally, the visual feedback is preferred over prior art metronome type timing devices which the student attempts to follow and match repeating audible signals that represent the desired frequency of compression. By remaining a passive feature, the visual indicators can be ignored until it is desired by the student or instructor. Further, the real time feedback regarding the compression rate performed is believed superior to other methods which record the compression rate, but the record can only be reviewed after the training exercise is completed. With the present rate indicator device **60**, the student can view the visual indicators **64** while the compressions are in progress, and make concurrent adjustments and improve training performance during the exercise. Also, the CPR rate indicator **60** may be configured to respond with positive visual feedback only when both the compression rate being performed by the student and the depth of compression into the core portion **46** are properly achieved.

FIG. 15 provides a schematic illustration of the electrical circuit of the CPR rate indicator **60**, which includes a conventional microprocessor unit **70** for recording and calculating the desired measurements described, the desired visual indicators **64a-c**, audio indicators, controllers, such as automatic on and off controls, and a power supply. The device is battery operated, with an operating voltage range of between 2.20VDC and 5.5VDC, meaning that either 2 or 3 conventional batteries may optionally be designed for use. The indicator **60** is preferably provided as a series of LED or other lights which would be located at any position which is visible to the student during the application of compressions to the manikin, but preferably would be provided within a slot or window **62** positioned near the shoulder of the manikin device **10** as shown in FIGS. 1 and 3.

Upon approaching the present manikin device having a CPR compression rate indicator **60**, the indicator may be in the off mode. Upon an initial compression such that the sensor **66** engages the electrical contacts **67**, **68**, the rate indicator is automatically moved to on mode of operation. During initial student compressions on the manikin device **10**, **10'**, the visual display would only provide a red light **64a**. The indicator **60** waits during the initial compressions until the student begins to perform at a regular compression speed. After a few data points are collected using sensors **66** interconnected with the indicator device **60**, a real time moving average of the speed of compressions is measured and calculated by the microprocessor unit **70**. Later during the compression exercise, a different number of points are collected for averaging. To collect such compression data, the electrical sensor **66** is provided as shown in FIG. 16 at the center of the manikin

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torso **14** with a wire contact **67** extending to the indicator module **60** for recording the number, speed and depth of compressions. The electrical sensors **66** may be provided for engagement with posts **68** supporting the wire contact **67**. The posts **68** are of a specific height such that engagement of the contact with the posts by the student ensures that the desired compression depth has been achieved by the student to simulate heart compression. After the last compression is sensed by the sensor **66**, a timer within the indicator **60**, generally shown within the microprocessor **70** in FIG. 15, is activated which may be customized to a desired time period. After the passage of the desired time, if no compressions are sensed, the indicator **60** is automatically moved to the off or sleep mode. In sleep mode, the device draws only about 1 micro Amp ( $\mu$ A) of current. Thus, the use of such a novel timer and sleep mode in the indicator **60** enables the present manikin device **10**, **10'** to achieve longer battery life. The use of the timer is ideal in a teaching environment, since an instructor or student need not specifically turn the manikin device on or off, as the device **60** is able to wake itself up from a low power consumption sleep mode. In the illustrated preferred embodiment, the training device does not include an on/off switch.

The CPR indicator **60** must accurately display the rate of CPR compressions performed on the device **10**, **10'**, thus a microcontroller (MCU) is preferred in the illustrated circuit of FIG. 15. Since the compression rate is a function of time, the clock source must be accurate and a resonator is preferable over a simple resistor/capacitor network, which has very wide tolerances and in many cases is also temperature dependent. An oscillator network is connected to pins **13** and **14** of the microcontroller as shown in FIG. 15. Because there is no on/off switch in the circuit, it is technically always powered by the batteries, and low power consumption of 1  $\mu$ A during sleep mode is essential. A metal-oxide semiconductor field-effect transducer or MOSFET is preferred in the current design for reverse battery protection, as in FIG. 15, since, unlike a diode, the MOSFET minimizes the voltage drop across it to maximize run time.

Once the device is in sleep mode, it is activated or reactivated when the bellows **74** is pressed at least one time. Pressing the bellows **74**, closes a set of electrical contacts across the bell1 and bell2 connection points shown in FIG. 15, and the microcontroller is awakened from sleep mode using wakeup pin **15**. Pin **9** is provided as an interrupt pin to measure the time between each compression (which is the closing of a switch). A minimum of two compressions are required to be made before a compression rate may be calculated. After the second compression, the rate will be displayed using the LED's, which is generally the red LED **64a**. The LED's which are later illuminated depend on the very last two compressions which are received. When the compressions stop, the microcontroller detects that the rate has fallen out of range or specification, and the red LED **64a** is illuminated. If no more compressions are made, the circuit moves to sleep mode and all visual indicators **64** are turned off.

Although the medical training device of the present application has been described in detail sufficient for one of ordinary skill in the art to practice the invention, it should be understood that various changes, substitutions and alterations may be made without departing from the spirit or scope of the device as defined in the attached claims. Moreover, the scope of the present device is not intended to be limited to the specific embodiments described here, which are provided by way of example. As one of ordinary skill in the art will readily appreciate from the disclosure of the present device and its embodiments, other components and means presently existing or later to be developed that perform substantially the

same function to achieve substantially the same result as those of the corresponding embodiments described here, may be utilized according to the present application. Accordingly, the appended claims are intended to include within their scope such other components or means.

We claim:

1. An improved medical training device comprising,
  - a) a torso portion having a compressible core section and a removable pliable cover section, which core and cover sections are interconnected;
  - b) a head portion interconnected with said torso portion, and having a fixed, non-movable, back half section and a movable front half face section which are pivotably interconnected near simulated ear sections;
  - c) attachment portions located on said front face section and projecting therefrom for attachment of a lung bag or a face shield; and
  - d) a CPR rate indicator, integral with the device, for directly providing real time feed back to a person being trained on said device of the rate of CPR compressions being performed.
2. A training manikin comprising,
  - a) a torso portion having a core section comprising a continuous volume filled by a compressible material that is compressed during operation of the manikin, and a removable pliable cover section, each substantially surrounded by a rigid frame member and said core and cover sections are interconnected along one portion of each of said rigid frame members;
  - b) a head portion interconnected with said torso portion, and having a non-movable, fixed back half section and a movable front half face section which are pivotably interconnected; and
  - c) an integral CPR rate indicator module comprising at least two indicators for providing real time feedback to a student of their rate of CPR compressions during a training exercise and wherein the module includes an automatic power on feature which is prompted to turn the module power to on mode by an initial CPR compression.
3. The training manikin of claim 2 wherein said core and cover sections of said torso portion are interconnected at a pivoting hinge located on one portion of each of said rigid frame members.
4. A training manikin comprising,
  - a) a torso portion having a core section comprising a continuous volume filled by a compressible material that is compressed during operation of the manikin, and a removable pliable cover section, each substantially surrounded by a rigid frame member and said core and cover sections are interconnected along one portion of each of said rigid frame members;
  - b) a pivotable head portion interconnected with said torso portion; and
  - c) an integral CPR rate indicator module comprising at least two indicators for providing real time feedback to a student of their rate of CPR compressions during a training exercise, and wherein the module includes an automatic power on feature which is prompted to turn the module power to on mode by an initial CPR compression.

5. The training manikin of claim 4 with the CPR rate indicator module further comprising three different indicators for providing real time feedback of CPR compression rates.

6. The training manikin of claim 4 or 5 wherein the CPR rate indicator module indicators are visual indicators or audio indicators.

7. The training manikin of claim 6 wherein the CPR rate indicator module visual indicators are colored red, yellow and/or green lights.

8. An improved medical training device comprising,
 

- a) a torso portion having a compressible core section and a removable pliable cover section, which core and cover sections are interconnected;

b) a head portion interconnected with said torso portion, and having a fixed, non-movable, back half section and a movable front half face section which are pivotably interconnected near simulated ear sections;

c) attachment portions located on said front face section and projecting therefrom for attachment of a lung bag or a face shield; and

d) a CPR rate indicator module integral with the device having at least two indicators for directly providing real time feed back to a person being trained on said device of the rate of CPR compressions being performed during a training exercise, and the indicator module includes an automatic on feature which is prompted to the on mode by a CPR compression.

9. An improved medical training device comprising,
 

- a) a torso portion having a compressible core section and a removable pliable cover section, which core and cover sections are interconnected;

b) a head portion interconnected with said torso portion, and having a fixed, non-movable, back half section and a movable front half face section which are pivotably interconnected near simulated ear sections;

c) attachment portions located on said front face section and projecting therefrom for attachment of a lung bag or a face shield; and

d) a CPR rate indicator, integral with the device, for directly providing real time feed back to a person being trained on said device of the rate of CPR compressions being performed, with the CPR rate indicator being positioned for viewing during performance of CPR compressions through a window formed in the device.

10. An improved medical training device comprising,
 

- a) a torso portion having a compressible core section and a removable pliable cover section, which core and cover sections are interconnected;

b) a head portion interconnected with said torso portion, and having a fixed, non-movable, back half section and a movable front half face section which are pivotably interconnected near simulated ear sections;

c) attachment portions located on said front face section and projecting therefrom for attachment of a lung bag or a face shield; and

d) a CPR rate indicator, integral with the device, for directly providing real time feed back to a person being trained on said device of the rate of CPR compressions being performed, with the CPR rate indicator positioned for viewing during performance of CPR compressions through an opening formed in the removable pliable cover section of the torso portion of the device.